Remarks

I. The Claims

Upon entry of the foregoing amendment, claims 1, 6-13, 19, 24-37 and 64-80 are pending in the application, with claims 1 and 35 being the independent claims. Claims 2-4 and 14-17 are sought to be cancelled. No new matter is added by way of these amendments. It is respectfully requested that the amendments be entered and considered.

II. Withdrawn Rejections

Applicants appreciate and acknowledge that the Examiner has withdrawn the rejection of claims 1 and 24 under 35 U.S.C § 112, second paragraph. (Office Action, page 2.)

Applicants appreciate and acknowledge that the Examiner has withdrawn the rejection of claims 1, 6-13, 24 and 35 under the judicially created doctrine of obviousness-type double patenting over claims 1-2 and 7 of U.S. Patent Application 11/671,498. (Office Action, page 2.)

Applicants appreciate and acknowledge that the Examiner has withdrawn the rejection of claims 1, 6-13, 24 and 35 under the judicially created doctrine of obviousness-type double patenting over claims 1-2 and 6-7 of U.S. Patent No. 7,192,580. (Office Action, page 3.)

Applicants appreciate and acknowledge that the Examiner has withdrawn the rejection of claims 1, 6-13 and 35 under 35 U.S.C § 102(a) and § 103(a) over Roberts *et al.* (WO99/18799). (Office Action, page 3.)

III. Allowable Subject Matter

Applicants appreciate and acknowledge the Examiner's indication that claim 78 is allowable if rewritten as an independent claim. (Office Action, page 18.)

IV. A Biological Deposit Is Not Required for Enablement

The Examiner states,

> [c]laims 27-31 and 73-77 are rejected under 35 U.S.C. 112, first paragraph, for failing to meet the biological deposit requirements.

(Office Action, page 3.) The Examiner further states,

> [t]he deposit of biological organisms is considered by the Examiner to be necessary for the enablement of the current invention (see 37 CFR 1.808(a)).

(Office Action, page 4.) Applicants respectfully disagree that a deposit is necessary for the enablement of the present claims.

Applicants remind the Examiner, with regards to an enablement rejection, "[t]he evidence provided by applicant need not be conclusive but merely convincing to one skilled in the art." (MPEP 2164.05 (eighth edition, September 2007); underlining in original.)

Applicants incorporate by reference remarks, relevant to this rejection, from Applicants' previous Replies. Additionally, Applicants emphasize that in the outstanding Office Action and previous Office Actions the Examiner has only made conclusory statements related to these claims as not meeting the enablement requirement without a biological deposit. The Examiner has not, as required, provided reasons or evidence why deposits are necessary for the enablement of claims 27-31 and 73-77. Therefore, the Examiner has not made a *prima facie* case of non-enablement.

Furthermore, the Examiner states the "Applicant has failed to demonstrate that the VSV strains designated M1, M2, M3, M4 and M5 are well known and **readily** available to the public **without restriction**." (Office Action, page 4; emphasis in original.) Applicants respectfully disagree and have previously presented arguments that provide a *prima facie* showing that the VSV strains recited in claims 27-31 and 73-77 are well known and readily available to the public.

The MPEP states,

> [i]n an application where the invention required access to specific biological material, an applicant could show that the biological material is accessible because it is known and readily available to the public. The concepts of "known and readily available" are considered to reflect a level of public accessibility to a necessary component of an invention disclosure that is consistent with an ability to make and use the invention . . . . Unless there is a reasonable basis to believe that the biological material will cease to be available during the enforceable life of the patent, current availability would satisfy the requirement . . . . **If an applicant**

has adequately established that a biological material is known and readily available, the Office will accept that showing.

(MPEP § 2404.01 (eighth edition, September 2007); underlining and bolding added.)

Regarding whether the biological material is readily available, Applicants have previously shown that a review of the scientific literature indicates that a variety of researchers have had access to the VSV strains of claims 27-31 and claims 73-77.[1] Additionally to further show that the claimed biological materials are readily available, Applicants previously submitted examples of the policies for most of the journals which published the relevant scientific literature provided previously by Applicants.[2] These policies indicate these journals require their authors to agree to make biological materials available to the scientific community. Since the strains are generally available to researchers in the field, Applicants respectfully submit that deposit under the terms of the Budapest Treaty is not necessary to meet the enablement requirement.

Therefore, Applicants have (i) clearly shown and presented evidence that the VSV strains recited in claims 27-31 and 73-77 are well known and readily available to the public[3] and (ii) the Examiner has not, as required (*e.g.*, see MPEP § 2404.01), provided a reasonable basis to believe that the biological materials are not readily available and will cease to be available during the enforceable life of the patent. In other words, Applicants have presented a *prima facie* case that the biological materials cited in the claims are accessible because they are known and readily available to the public. The Examiner has not provided any evidence or reasoning to rebut this. Therefore, a biological deposit cannot be required.

Even though Applicants believe that the above completely rebuts the Examiner's rejection, Applicants assert that the VSV strains of claims 27-31 and 73-77 are sufficiently described in the specification and in the art, at the time of the invention, so that one skilled in the art could make and/or use the VSV strains of claims 27-31 and 73-77. For example, Table 11, Figures 14-23, Example 27 and the Sequence Listing of Applicants' specification provide both

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1 For example, see Applicants' Reply of April 7, 2008, page 12.
2 For example, see Applicants' Reply of April 7, 2008, page 13 and Appendix A.
3 For example, see Applicants' Reply of April 7, 2008, pages 11-14.

nucleic acid and amino acid sequence information for viruses that are the subject matter of claims 27-31 and 73-77.

In summary, Applicants have clearly demonstrated and presented *prima facie* evidence that the viruses recited in claims 27-31 and 73-77 are readily available in the art. The Examiner has not presented any credible reasons or evidence why they would not continue to be readily available. **Without credible reasons or evidence why they would not continue to be readily available, the burden remains with the Examiner to show that claims 27-31 and 73-77 are not enabled.** (MPEP § 2404.01.)

In view of the above, Applicants respectfully request the Examiner reconsider and withdraw the rejection of claims 27-31 and 73-77 under 35 U.S.C. § 112, first paragraph.

V. Claimed Invention is Enabled

Claims 1, 6-13, 19, 24-37, 64-77 and 79-80 were rejected under 35 U.S.C. § 112, first paragraph, because:

> the specification, while being enabling for methods utilizing attenuated VSV for reducing the viability of hematopoietic tumor cells *in vitro* and the use of attenuated VSV to reduce the viability of tumor cell based xenographs in immunodeficient mice, does not reasonably provide enablement for the utilization [of] attenuated VSV for the reduction of viability of all types of hemapoietic tumor cells to reduce the viability of a tumor cell in an immunocompetent animal.

(Office Action, page 5.) Applicants respectfully disagree.

The purpose of the enablement requirement is to ensure that the specification describes the invention in such terms that one skilled in the art can make and use the invention commensurate with the scope of the claims. (*E.g.*, see MPEP § 2164 (eighth edition, September 2007).)

Applicants believe the Examiner's enablement rejection is focused on : (i) the type of hematopoietic tumor cell and (ii) therapeutic treatment.

Applicants incorporate by reference Remarks, related to this rejection, from Applicants' previous Reply of April 7, 2008, instead of repeating them here. Applicants request that the Examiner review and reconsider the previous Remarks and those below.

The Examiner still seems to be focused on whether Applicants' specification has enabled claims directed to treating cancer and/or efficacy in a human[4] and bases the enablement rejection, at least in part, on the alleged unpredictability of therapeutic results upon practice of the claimed invention. However, even though the practice of the claimed invention may result in a therapeutic benefit, **the subject matter of the claims relates to "reducing the viability of a tumor cell". The present claims do not recite or require any "efficacy" or "therapeutic effect".**

In the initial paragraph of the enablement rejection, the Examiner refers to reducing the viability of a tumor cell, but then focuses on arguments and documents allegedly showing that certain models and/or experiments do not correlate with efficacy or treatment in humans. For example, the Examiner states,

> Gura . . . teach that xenographs are not good models for determining the efficacy of a treatment modality . . . . Gura illustrates the lack of correlation between efficacy in xenograft model systems and in vivo efficacy in humans.

(Office Action, page 12, underlining added.) However, the Examiner has not expressed specific reasons why one skilled in the art, upon review of Applicants' specification would not have expected the claimed methods to result in the reduction of the viability of a tumor cell *in vivo* or in an immunocompetent animal. Additionally, Applicants have previously provided various reasons and evidence showing that one skilled in the art would have expected the claimed methods to result in the reduction of the viability of a tumor cell *in vivo* or in an immunocompetent animal.[5] For example, Applicants' previous Replies have shown that numerous tumor cell lines, representing at least 9 different tumor types, are susceptible to VSV

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[4] For clarity, Applicants believe that, if presented, similar claims to treating hematopoietic tumor cells are enabled by the present application.

[5] For example, see Applicants' Replies of (i) April 7, 2008, pages 14-18 and Appendices B & C; and (ii) August 2, 2007, pages 11-22 .

infection.[6] This represents a wide range of tumor cell types and therefore demonstrates enablement commensurate with the scope of the present claims.

Furthermore, the specification teaches characteristics for which one skilled in the art can, without undue experimentation, screen a particular hematopoietic tumor cell type to confirm its sensitivity to VSV, *e.g.*, screen for reduced or no activity of (i) PKR, (ii) PML (iii) STAT1, and/or (iv) interferon regulatory factor (IRF-1) and/or interferon (see *e.g.*, page, 4 lines 8-22; page 11, lines 21-27; page 12, line 7 to page 16, line 22; and Example 1).[7] For example, "results obtained for Table 1 demonstrate that a screening strategy for determining the types of tumours which are susceptible to killing by VSV may be employed". (Specification, page 29, lines 29-31.) The level of testing taught in the application and known in the art is well within the capabilities of one skilled in the art, at the time of filing, and would not require undue experimentation.

Additionally, Applicants refer to their copending U.S. Patent Application No. 11/685,483 ('483 application), which claims priority to the present application and is before the same Examiner as the instant application. Claim 1 of this related application recites:

> [a] method of reducing the viability of a tumor cell, comprising administering to the tumor cell a vesicular stomatitis virus,
> wherein said tumor cell is a carcinoma,
> wherein the virus is contained in a cell infected with the virus, and
> wherein the administering comprises administering the virus-infected cell.

The tumor cell in this claim is a carcinoma, whereas the tumor cell in claim 1 of the present application is a hematopoietic tumor cell. In an obviousness rejection of, *inter alia*, claim 1 of the '483 application, the Examiner states that "the use of VSV as a cancer treatment is well known in the art yielding predictable results". (April 10, 2008 Office Action, page 21, for U.S. Patent Application No. 11/685,483.)

Something well known in the art yielding predictable results is clearly enabled. If the use of VSV as a cancer treatment is well known in the art yielding predictable results, then it follows

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[6] For example, see Applicants' Replies of (i) November 24, 2004, pages 4-6 and Tables A & B and (ii) August 2, 2007, pages 15-17.

[7] For clarity, with the exception of claims 19 and 71, Applicants' invention, as claimed herein, is not limited to reducing the viability of tumor cells with these characteristics.

that, at the time of the invention as claimed herein, one skilled in the art upon review of Applicants' specification would consider that a method, as claimed herein, of reducing the viability of a tumor cell comprising administering to the tumor cell a vesicular stomatitis virus infected cell is clearly enabled.

Therefore, based on Applicants' Remarks and/or as confirmed by the Examiners' own admission, claims 1, 6-13, 19, 24-37, 64-77 and 79-80 are enabled.

Applicants' Reply of April 7, 2008 also referred to *Ex parte* Saito and Zhao (Appeal No. 2005-1442 before the Board of Patent Appeals and Interferences (BPAI), not binding precedent of the Board) and *Ex parte* Boutin (Appeal No. 2006-1879 before the BPAI, not binding precedent of the Board), which both stand for the proposition that unless the claims explicitly refer to a therapeutic benefit, typically the Examiner should not determine if the claims are enabled for an unclaimed therapeutic benefit. The Examiner responded that, "contrary to applicant's assertion, the reduction in the viability of a tumor cell in the context of a living being . . . constitutes a therapeutic response." (Office Action, page 6.) In the following paragraph of the Office Action, the Examiner attempts to distinguish the present situation from these two board decisions in that they "are not germane to the instant application as . . . the instant claims refer to a therapeutic response." (Office Action, page 6.) Applicants agree that in some cases practice of the methods claimed herein may result in a therapeutic result, but do not agree that the claims refer to a therapeutic response.

In addition to the two BPAI decisions referred to above, Applicants refer the Examiner to *Ex parte Ayishi* (Appeal No. 2006-1608 before the BPAI, not binding precedent of the Board, Appendix A). This case is similar to the present case in that the claims do not specifically recite or require a therapeutic effect, but recite a method that may encompass methods achieving a clinically effective therapeutic response. In *Ex parte Ayisi* the Board stated,

> The invention that must be enabled to satisfy § 112 is the invention defined by the claims. See CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.). Thus, when the claims are not limited to a method that achieves

> therapeutic or clinical efficacy, such efficacy is not required for the claims to be enabled.
>
> Here, the claims are directed to a method comprising [ ] contacting a virus-infected cell with an extract from Ocimum gratissimum in an amount effective to inhibit cytopathic effects of the virus in the cell (claim 31). Thus, while it is fair to say that the claims encompass a method that achieves a clinically effective therapeutic response, they do not require it. Cf. In re Cortright, 165 F.3d 1353, 49 USPQ2d 1464 (Fed. Cir. 1999) (claims to a method of treating scalp baldness could be enabled even if the method did not produce a full head of hair).
>
> We conclude that the potential problems identified by the examiner may indeed complicate treatment of a HIV in a patient, but such problems need not be overcome in order to contact[ ] a virus-infected cell with an extract from Ocimum gratissimum in an amount effective to inhibit cytopathic effects of the virus in the cell - all that is required by the claims. Thus, the examiner has not adequately explained why practicing the claimed method would have required undue experimentation.
>
> Moreover, a claim may encompass inoperative embodiments and still meet the enablement requirement of 35 U.S.C. § 112, first paragraph. See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984), In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976), In re Cook, 439 F.2d 730, 732, 169 USPQ 298, 300 (CCPA 1971). And the stage at which an invention in this field become useful is well before it is ready to be administered to humans. In re Brana, 51 F.3d 1560, 1568, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995). (While the Brana court referred to usefulness, the rejection on appeal was for nonenablement. See id. at 1564, 34 USPQ2d at 1439.)
>
> Therefore, as the examiner has failed to set forth a prima facie case of unpatentability under 35 U.S.C. § 112, first paragraph, we are compelled to reverse the rejection.

(*Ex parte Ayisi,* pages 5-7, underlining in original; quotation remarks removed.) Applicants assert that the enablement issues of *Ex parte Ayisi* are relevant, at least in part, to those in the present application. Previously the Examiner distinguished *Ex parte* Saito and Zhao and *Ex parte* Boutin because they allegedly "are not germane to the instant application as . . . the instant claims refer to a therapeutic response." (Office Action, page 6.)[8] In the case of *Ex parte Ayisi*, the claims refer to a method comprising contacting a virus-infected cell with an extract from Ocimum gratissimum in an amount effective to inhibit cytopathic effects of the virus in the cell,

[8] As previously stated herein, practice of the claimed methods may result in a therapeutic result, but do not refer to a therapeutic response.

whereas the present claims refer to methods of reducing the viability of a tumor cell, comprising administering to the tumor cell a vesicular stomatitis virus.

In view of the above, Applicants respectfully request the Examiner reconsider and withdraw the rejections under 35 U.S.C. § 112, first paragraph.

Conclusion

It is not believed that extensions of time are required beyond those that may otherwise be provided for herein or in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, The United States Patent and Trademark Office is hereby authorized to charge any fee deficiency required to prevent abandonment of the current application or credit any overpayment to Deposit Account 50-1677.

Applicants believe that a full and complete Reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

/Douglas A. Golightly/

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Date: September 16, 2008

Appendix A

Ex parte Ayishi (Appeal No. 2006-1608)

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte NANA K. AYISI

Appeal No. 2006-1608
Application No. 09/978,593

ON BRIEF

Before SCHEINER, MILLS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 20, 22, 31 and 32, which read as follows:

20. The method according to claim 31, wherein the virus is human immunodeficiency virus (HIV), herpes simplex virus (HSV), human cytomegalovirus (HCMV), poliovirus (PV), measles virus (MV) or yellow fever virus (YMV).

22. The method according to claim 20, wherein the virus is HIV-1, HCMV, HSV-1 or HSV-2.

31. A method comprising: contacting a virus-infected cell with an extract from Ocimum gratissimum in an amount effective to inhibit cytopathic effects of the virus in the cell.

32. The method according to claim 20, wherein the virus is HIV.

Claims 20, 22, 31 and 32 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification fails to provide an enabling disclosure. In addition, claims 20 and 31 stand rejected under 35 U.S.C. § 102(b) as being anticipated by El-Said[1] as evidenced by Merck.[2] After careful review of the record and consideration of the issues before us, we reverse both rejections.

DISCUSSION

Claims 20, 22, 31 and 32 stand rejected under 35 U.S.C. § 112, first paragraph, "because the specification, while being enabling for inhibiting HIV viral replication in Vero cells and Molt4 clone 8 cells with an extract of O. gratissimum, does not reasonably provide enablement for the O. gratissimum extract to inhibit HIV viral replication in a mammal or any other cell line. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims." Examiner's Answer, page 3.

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[1] El-Said et al. (El-Said), "An investigation into the efficacy of Ocimum gratissimum as used in Nigerian native medicine," Planta Medicine, pages 195-200 (1969).

[2] Merck Manual (Merck), Beers et al., editors, published by Merck Research Laboratories, Whitehouse Station, NJ, pp. 1293-1296, 1303-1306, 1312-1323, 2320-2324 and 2341-2343 (1999).

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Id. at 224, 169 USPQ at 370. Here, the examiner has not provided "acceptable evidence or reasoning which is inconsistent" with the specification, and therefore has not met the initial burden of showing nonenablement.

While the examiner engages in a Wands analysis, see In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988) (noting that facts that should be considered in determining whether a specification is enabling include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims), the examiner's primary concern appears to

be that "the use of in vitro tests is not an acceptable predicator of in vivo activity when claiming treatments to HIV." Examiner's Answer, page 6.

According to the examiner, the "[c]haracteristics of a compound's activity in vitro using purified or partially purified components generally differs significantly with the compound when used in a living body." Id. at 3. The examiner asserts that clinical correlation of in vitro activity to in vivo efficacy is generally lacking, as cultured cell lines "differ significantly from in vivo animal models." Id. at 4.

Moreover, as explained by the examiner, "[t]he greatly increased complexity of the in vivo environment as compared to the very narrowly defined and controlled conditions of an in vitro assay does not permit a single extrapolation of in vitro assays to human diagnostic efficacy with any reasonable degree of predictability." Id. The examiner cites Planchon,[3] Kerr[4] and Chomienne[5] to demonstrate the lack of correlation of in vitro testing to in vivo efficacy. See id. at 5. The examiner then cites a statement by Joanne Shellenbach, a spokeswoman for the American Cancer Society, quoted in the

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[3] Planchon et al. (Planchon), "Differential Effects of Butyrate Derivatives on Human Breast Cancer Cells Grown as Organotypic Nodules in Vitro and as Xenografts in Vivo," In Vivo, Vol. 6, pp. 605-10 (1992).

[4] Kerr et al. (Kerr), "The relationship between Cytotoxic Drug Exposure and Tumour Cell Kill, in Vitro and in Vivo," In Vivo, Vol. 5, pp. 385-88 (1991).

[5] Chomienne et al. (Chomienne), "Discrepancy Between in Vitro and in Vivo Passaged U-937 Human Leukemic Cells: Tumorigenicity and Sensitivity to Differentiating Drugs, " In Vivo, Vol. 2, pp. 281-88 (1988).

Washington Times,[6] stating that results in animal models "'cannot always be easily replicated in humans.'" Id.

The examiner next cites Kirsi[7] for its teaching that "[t]he effect of an inhibitor is also dependent on the virus, inhibitor concentration and cell line used," indicating that an "inhibitor may be effective in one cell line but not in another cell line for the same virus." Id. at 6. Finally, the examiner cites Mitsuya[8] and Sandstöm[9] as evidence that a drug that showed promise as a treatment of HIV in vitro, suramin, was not correlated to in vivo efficacy. See id.

The invention that must be enabled to satisfy § 112 is the invention defined by the claims. See CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) ("Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect."). Thus, when the claims are not limited to a method that achieves therapeutic or clinical efficacy, such efficacy is not required for the claims to be enabled.

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[6] Joyce Howard Price, Researchers test 'smart-bomb' cancer therapy, Washington Times, November 16, 2001, at 3.

[7] Kirsi et al. (Kirsi), "Broad-Spectrum Antiviral Activity of 2-β-D-Ribofuranosylselenazole-4-Carboxamide, a New Antiviral Agent," Antimicrobial Agents and Chemotherapy, Vol. 24, No. 3, pp. 353-61 (1983).

[8] Mitsuya et al. (Mitsuya), "Suramin Protection of T Cells in Vitro Against Infectivity and Cytopathic Effect of HTLV-III," Science, Vol. 226, pp. 172-74 (1984).

[9] Sandstöm et al. (Sandstöm), "Antiviral Therapy in AIDS Clinical Pharmacological Properties and Therapeutic Experience to Date," Drugs, Vol. 34, pp. 372-90 (1987).

Here, the claims are directed to a "method comprising [ ] contacting a virus-infected cell with an extract from Ocimum gratissimum in an amount effective to inhibit cytopathic effects of the virus in the cell" (claim 31). Thus, while it is fair to say that the claims encompass a method that achieves a clinically effective therapeutic response, they do not require it. Cf. In re Cortright, 165 F.3d 1353, 49 USPQ2d 1464 (Fed. Cir. 1999) (claims to a method of "treating scalp baldness" could be enabled even if the method did not produce a full head of hair).

We conclude that the potential problems identified by the examiner may indeed complicate treatment of a HIV in a patient, but such problems need not be overcome in order to "contact[ ] a virus-infected cell with an extract from Ocimum gratissimum in an amount effective to inhibit cytopathic effects of the virus in the cell" - all that is required by the claims. Thus, the examiner has not adequately explained why practicing the claimed method would have required undue experimentation.

Moreover, a claim may encompass inoperative embodiments and still meet the enablement requirement of 35 U.S.C. § 112, first paragraph. See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984), In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976), In re Cook, 439 F.2d 730, 732, 169 USPQ 298, 300 (CCPA 1971). And the stage at which an invention in this field become useful is well before it is ready to be administered to humans." In re Brana, 51 F.3d 1560, 1568, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995). (While the Brana court referred

to "usefulness", the rejection on appeal was for nonenablement. See id. at 1564, 34 USPQ2d at 1439.)

Therefore, as the examiner has failed to set forth a prima facie case of unpatentability under 35 U.S.C. § 112, first paragraph, we are compelled to reverse the rejection.

Claims 20 and 31 stand rejected under 35 U.S.C. § 102(b) as being anticipated by El-Said.

According to the rejection,

> El-Said [ ] disclose[s] that an aqueous extract of O. gratissimum has been used in Nigerian herbal medicine for the treatment of fevers (see abstract). Fever is a symptom that is associated with viral or bacterial infections (as evidenced by . . . Merck . . .). Thus, the treatment of viral infection using an extract of O. gratissimum is anticipated by El-Said [ ].

Examiner's Answer, page 7.

The burden is on the examiner to set forth a prima facie case of unpatentability. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996). In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997).

Appellant argues that El-Said "disclose[s] the chemotaxonomy and antibacterial testing of Ocimum gratissimum specimens." Appeal Brief, page 11 (emphasis in original). Therefore, according to appellant, "[t]he invention, as claimed, is not anticipated by [El-Said] because the reference does not disclose

anti-viral testing and/or a method of use of Ocimum gratissimum for inhibiting the cytopathic effects of a virus-infected cell." Id. at 12. We agree, and the rejection is reversed.

CONCLUSION

Because the examiner has failed to set forth a prima facie case of unpatentability, both rejections of record are reversed.

REVERSED

Toni R. Scheiner Administrative Patent Judge	)
	) BOARD OF PATENT
Demetra J. Mills Administrative Patent Judge	) APPEALS AND
	) INTERFERENCES
Lora M. Green Administrative Patent Judge	)

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